DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
5072d

60 8th Street, N.E.
Atlanta, Georgia 30309

September 28, 2004

VIA FEDERAL EXPRESS

Jay C. Garmon
President
Ideal Optics, Inc.
225 Cumberland Parkway SE
Suite 500
Atlanta, Georgia 30339

WARNING LETTER
(04-ATL-23)

Dear Mr. Garmon:

An inspection of your facility was conducted on August 4-12, 2004, by Investigator Derek C. Price. Our investigator found that you continue to manufacture soft daily wear contact lenses. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigator documented several significant deviations from the Quality System Regulation (QSR) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 820. These deviations cause the devices you manufacture to be adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, and storage are not in conformance with the QSR as follows:

You have failed to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria [21 CFR 820.80(d)]. Our review of thirty-five device history records revealed five occasions when lots were released which failed to meet your stated sterilization parameters. These lots were #SF23 ([redacted] vials), QI25 ([redacted] vials), QH22 ([redacted] vials), QH08 ([redacted] vials), and QG29([redacted] vials). The sterilization records for these lots had not been reviewed by responsible individuals at your firm to determine if the appropriate parameters had been met. Your firm had failed to establish any procedures requiring any review of the sterilization information provided by your contract sterilizer. This failure caused these non-conforming products to be released for distribution.

You have failed to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications [21 CFR 820.70(a)]. You have failed to monitor critical production processes that directly impact upon product sterility. In addition to the lack of review noted above, there was no indication that any biological indicators had been used in the sterilization cycles. No biological indicator test results were available in the device history records reviewed. After contacting your contract sterilizer, it was learned that your contractor does not maintain any biological indicator records for any of your products.

You have failed to maintain device history records capable of demonstrating that that the devices are manufactured in accordance with the device master records and your established specifications [21 CFR 820.184]. This failure is exemplified by the missing biological indicator results in all of your available sterilization records. You have failed to establish written procedures which address what review should be conducted of these device history records prior to release of your devices.

Management with executive responsibility has failed to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirement of your established quality policy and objectives and the QSR [21 CFR 820.20(c)]. No procedures were available which addressed how these reviews were to be conducted, how often the reviews should be performed or who should participate in the review process. It was determined during the inspection that no documentation was available which would indicate when or if any such management reviews had occurred. This deviation was pointed out during the previous inspection.

You have failed to conduct quality audits at the intervals established in your procedures to verify that the quality system is effective in fulfilling your quality system objectives [21 CFR 820.22]. No audit had been conducted in the last twelve months as required by your Quality Control Audit Procedures. No documentation was available as to when the last quality audit had been conducted.

You have failed to establish and maintain a quality system that is appropriate for the specific medical devices you manufacture and distribute [21 CFR 820.5]. This failure is exemplified by the failure to appropriately review the sterilization records for your products, release of products labeled as sterile which did not receive the sterilization cycle established for your product, deficient or complete lack of quality control procedures, and your failure to conduct the quality audits and reviews discussed above.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. At the close of the inspection, the FDA 483 (Inspectional Observations) was issued to, and discussed with, you. The specific violations noted in this letter and in the FDA 483 could be symptomatic of serious underlying problems in your firm's manufacturing and quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the QSR deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your response should include the results of a retrospective review of your device history records to verify that all lots received an appropriate sterilization cycle. Your response to this letter should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead. You may contact Mr. Campbell at (404)253-1280 if you wish to set up a meeting at the district office to further discuss these issues.

Sincerely yours,

Mary Woleske

Mary H. Woleske, Director
Atlanta District